CONNECTING CASING SECTIONS OF AN ADMINISTERING APPARATUS FOR ADMINISTERING, IN DOSES, A PRODUCT WHICH CAN BE DELIVERED

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of International Application No. PCT/CH02/00412, filed on July 22, 2002, which claims priority to German Application No. 201 12 501.3, filed on July 30, 2001 and German Application No. 101 63 329.7, filed on December 21, 2001, the contents of all of which are incorporated herein in their entirety by reference.

BACKGROUND

The invention relates to administering devices and apparatus, and methods of their operation and use. The administering apparatus to which the invention relates can be inhalation apparatus, apparatus for oral ingestion of substances, including liquids, or other type of administering apparatus and the dosing portions thereof. In the case of administering apparatus comprising at least two casing sections, the invention relates to connecting the two casing sections. Examples of apparatus in accordance with the invention are injection apparatus, in particular injection pens and, more particularly, semi-disposable pens.

WO 97/17095 describes an injection apparatus consisting of a dosing and activating module and a reservoir module which are detachably connected to each other. The reservoir module is designed as a disposable module, while the dosing and activating module is intended to be re-used – once the reservoir module has been used – with a new reservoir module. The reservoir module contains a reservoir for a product to be injected and mounts a piston rod which acts on a piston accommodated in the reservoir, to deliver product. The piston rod comprises an outer thread which is in threaded engagement with an inner thread of a dosing setting member. The piston rod is linearly guided, such that when the dosing setting member is rotated, the piston rod is moved in an advancing direction towards the piston and a slight distance between a front end of the piston rod and the piston is thus changed. The dosing and activating module and the reservoir module are connected to each other by being screwed or clicked on.

An advantage of the design of the semi-disposable injection apparatus is that parts of the apparatus involved in dosing and delivery only have to be configured for delivering the contents

of a single reservoir. Since, if repeatedly used, such parts would always have to be guided back again to an initial position, they would furthermore be exposed to a risk of damage which is not to be underestimated. The reliability of correctly selecting and delivering the dosage need not therefore be less for semi-disposable injection apparatus than for completely re-usable apparatus. Moreover, exchanging a complete reservoir module is simpler than exchanging only a reservoir.

Assembling the dosing and activating module and a new reservoir module can nonetheless raise problems, in particular with regard to correctly selecting the dosage or dose for the first delivery of product or substance to be made once the modules are assembled. Because of the coupling between the piston rod, the dosage setting member and the dosing and activating module– provided for the purpose of dosing and delivering – there exists the danger that assembling the reservoir module and the dosing and activating module unpredictably effects the position of the dosage setting member or even of the piston rod. This problem can occur in any dosing and delivering mechanism in which the processes of dosing and delivering are performed separately, as is the case with injection apparatus. The problem is also not restricted to semi-disposable pens. Rather, this problem afflicts every administering apparatus in which the coupling between the piston rod or other driven member, the dosage setting member and a dosing and drive device – for dosing and delivery – is established by simply connecting two casing sections. Moreover, there is a desire – in particular when self-administering a product – for simplicity of handling, wherein simple handling not only advantageously increases the handling comfort, but also safety.

SUMMARY

An object of the present invention is to provide an administering device or apparatus having casing sections and a dosing and delivering mechanism, wherein the dosing and delivering mechanism has an initial state defined by assembling the casing sections, and to nonetheless simplify the assembly process.

In one embodiment, the present invention comprises an administering apparatus including a front casing section, a rear casing section connectable to the front casing section, a driven member carried by at least one of said casing sections for performing a delivery movement, a dose setting member for performing a dosing movement relative to the driven member to select

said product dosage, and a dosing and drive device moveable rotationally about a rotational axis and translationally relative to the front casing section, wherein, when connecting the casing sections, the dosing and drive device is coupled to the driven member and the dose setting member such that a rotational movement of the dosing and drive device causes the dosing movement of the dose setting member and a translation movement of the dosing and drive device causes the delivery movement of the driven member, wherein at least one axial guide is formed on one of the casing sections and at least one engagement element is formed on the other of the casing sections such that when connecting the casing sections, the casing sections are slid onto each other as far as a connecting end position and cannot rotate relative to each other.

In the case of an administering apparatus comprising at least two casing sections and a dosing and delivering mechanism the component parts of which are coupled to each other by assembling the casing sections, it is an object of the invention to obtain a defined initial state of the dosing and delivering mechanism by assembling said casing sections and to nonetheless simplify assembly.

The invention relates to connecting a front casing section and a rear casing section of an administering apparatus, preferably an injection apparatus, which allows a product to be administered in a dosage or a number of dosages which can be selected. Accordingly, the injection apparatus comprises the front casing section and the rear casing section. The product is contained in a reservoir. The front casing section can form the reservoir directly, however, in some preferred embodiments, a container accommodated by the front casing section, for example a standard ampoule, forms the reservoir.

The administering apparatus further comprises a driven member which is mounted by at least one of the casing sections, preferably the front casing section, such that it can perform a delivery movement by which a product dosage selected beforehand is delivered from the reservoir. Since the product is usually delivered by a piston accommodated in the reservoir moving in an advancing direction towards an outlet of the reservoir, a piston rod preferably forms the driven member of a dosing and delivery mechanism of the administering apparatus. The driven member may comprise two pieces connected fixedly, i.e., permanently, or can be formed as a one piece structure. In one preferred embodiment, the piston and the driven member

are embodied as separate components, and a front end of the driven member pushes against a rear side of the piston for the purpose of delivering product.

Furthermore, a dosage setting member forms part of the administering apparatus, serving to select the product dosage. For this purpose, the dosage setting member performs a dosing movement relative to the driven member and also relative to the front casing section. If the product is delivered by means of the piston and piston rod, then the dosing movement of the dosage setting member sets the maximum stroke of the piston rod for its delivery movement.

In some embodiments, the injection apparatus comprises a dosing and drive device which can be moved translationally and rotationally about a rotational axis, relative to the front casing section. The dosing and drive device is connected to the rear casing section before the casing sections are assembled. The rear casing section can form a dosing element of the dosing and drive device, in that it can be rotated relative to the front casing section about a common longitudinal axis, in a connecting end position which it assumes once the casing sections have been assembled, i.e., once the connection has been established. In some preferred embodiments, however, the rear casing section is fixed in the connecting end position such that it cannot move rotationally and translationally relative to the front casing section, and correspondingly does not adopt a dosing function. The dosing and drive device is coupled to the driven member and the dosage setting member when the connection between the front and rear casing section is established, in some embodiments, directly by the connection itself being established, such that once the connection has been established, a rotational movement of the dosing and drive device causes the dosing movement of the dosage setting member and a translation movement of the dosing and drive device causes the delivery movement of the driven member.

The driven member, the dosage setting member and the dosing and drive device can be coupled by each two of these components directly engaging in pairs, without interposing transfer members, as is preferred, but this does not rule out interposing one or a number of different transfer members.

In some embodiments, the dosage setting member is preferably coupled to the driven member and at least one of the casing sections, preferably the front casing section, such that it

can only perform the delivery movement jointly with the driven member and is moved counter to the advancing direction, relative to the driven member, by the rotational movement of the dosing and drive device. One direct engagement with the driven member is preferably a threaded engagement.

In some embodiments, the rotational movement of the dosing and drive device is preferably transferred into a rotational movement of the dosage setting member or the driven member about the same rotational axis, in order to obtain the dosing movement of the dosage setting member. In some preferred embodiments, the dosing movement of the dosage setting member can be a combined translational and rotational movement or a purely translational movement. The delivery movement of the driven member is preferably a translational movement in the same direction and, in some preferred embodiments, along the same translational axis as the translational movement of the dosing and drive device. In the following, the rotational movement of the dosing and drive device will also be referred to as the dosing movement and its translational movement will also be referred to as the delivery movement. In some embodiments, the rotational axis and the translational axis of the dosing and drive device are particularly preferably identical. The dosing member preferably likewise moves translationally along this axis.

In an exemplary, first preferred embodiment, the dosing and drive device engages directly, secured against rotating, with the driven member, in order – for the purpose of selecting the dosage – to firstly transfer the rotational movement onto the driven member and via the driven member onto the dosage setting member, such that the dosage setting member performs its dosing movement. In a second preferred embodiment, the dosing and drive device engages directly, secured against rotating, with the dosage setting member for the purpose of dosing, i.e., in this case, the dosage setting member participated in the rotational movement of the dosing and drive device, such that its dosing movement is composed of a rotational and a translational movement. In both embodiments, the driven member and the dosage setting member are coupled, preferably directly engaging, such that they perform the delivery movement jointly.

In accordance with some embodiments of the invention, at least one axial guide is formed on one of the casing sections and at least one engagement element is formed on the other of the

casing sections. The at least one axial guide and the at least one engagement element interlock with each other when the connection between the casing sections is established and also after the connection between the casing sections has been established, in order to form a linear guide for the casing sections. The linear guide ensures that when the connection between the casing sections is established, the casing sections are slid onto each other as far as a connecting end position, secured – in some preferred embodiments, absolutely – against rotating relative to each other with regard to the rotational axis of the dosing and activating device. Preferably, no relative movement is possible between the casing sections except for the movement of sliding onto each other. Sliding the casing sections onto each other, axially and linearly guided, makes assembling the apparatus particularly simple. Furthermore, when establishing the coupling between the dosing and activating device and the driven member and the dosage setting member, it prevents unintentional rotational movements of the casing sections relative to each other from transferring undesirable rotational movements onto the driven member and/or the dosage setting member, wherein said rotational movements could cause a dosing movement of the dosage setting member, even if only due to response movements of the dosing and activating device to such unintentional rotational movements between the casing sections.

If the front casing section and the rear casing section together form a latching means, in some embodiments, the latching means preferably comprises a latching block which only allows the two casing sections to be latched onto each other in a front end position of the dosing and drive device. In this case, axially guiding the casing sections onto each other in accordance with the invention has the other advantage that latching cannot be prevented by the fact that establishing the coupling moves the dosage setting member, when the casing sections are assembled. For the latter could have an effect on the front end position of the dosing and drive device.

For linearly guiding the casing sections, the at least one axial guide may be formed directly on, i.e., in or on top of, a surface area of one of the casing sections. In some preferred embodiments, the axial guide forms a guide channel for the at least one engagement element of the other of the casing sections. The at least one engagement element is guided tightly on both sides as it slides in the guide channel. The at least one engagement element also may be formed

directly on, i.e., in or on top of, a surface area of the other of the casing sections, as an axially short engagement cam or as an axially extended engagement rib.

In some embodiments, it may be advantageous if a number of axial guides are formed on the surface area of one of the casing sections, spaced from each other in the circumferential direction. The number of axial guides are expediently arranged, uniformly distributed over the circumference of the surface area. Forming a number of axial guides, in particular forming a number of axial guides arranged uniformly distributed over the circumference, makes aligning the casing sections easier, since the casing sections can be slid onto each other in a plurality of pre-set rotational angular positions. Merely for the sake of completeness, reference may be made to the fact that a number of engagement elements can also be provided on the other of the casing sections, in particular a number of engagement elements which are likewise uniformly distributed over the circumference.

In order to make aligning the two casing sections relative to each other easier with respect to their rotational angular position, in some embodiments a guide channel formed by the at least one axial guide can be tapered in a funnel-shaped widening at its end which when aligned faces the other of the casing sections. If two adjacently arranged protruding sections, for example ribs, each form an axial guide with their mutually facing side walls, then said protruding sections are tapered axially, so as to form the funnel-shaped widening. Furthermore, it is particularly advantageous if such protruding sections are tapered in the radial direction towards the surface area of their casing section, at their end facing the other of the casing sections. A combined axial and radial taper at the entrance of the axial guide, in particular into a guide channel, makes aligning the casing sections particularly easier. If a number of axial guides are provided on one of the casing sections, then a number of axial guides and possibly all the axial guides are tapered axially and possibly radially.

What has been said above with respect to the one or more axial guides applies equally to the at least one or more engagement elements of the other casing section.

If, before connecting the casing sections, the dosage setting member is connected to the front casing section and the dosing and drive device is connected to the rear casing section, as in

some preferred embodiments, then the dosage setting member and a dosing element or dosing and drive element of the dosing and drive device are held by their respective casing section in pre-set rotational angular positions relative to the respective casing section. They are axially and linearly guided in the respective rotational angular position by their casing section.

In some embodiments, the dosing element or dosing and drive element is held by the rear casing section in its discrete rotational angular positions by a releasable engagement, preferably a locking engagement. In some preferred embodiments, tthe engagement also simultaneously generates a clicking sound when the dosing element or dosing and drive element is moved from one rotational angular position to the next during its dosing movement, such that the dosing process is also acoustically indicated.

The dosage setting member can be linearly guided by the front casing section in a non-releasable guide engagement. If the dosing movement of the dosage setting member is a combined rotational and translational movement, then the dosage setting member must of course be releasably fixed in pre-set rotational angular positions. In this case, the engagement between the dosage setting member and the front casing section may likewise be a locking engagement. The pre-set rotational angular positions of the dosage setting member and the dosing element or dosing and drive element are adjusted to the axial guide of the casing sections, such that when the casing sections are axially slid onto each other, the coupling between the driven member, the dosage setting member and the dosing and drive device is established without rotation in each of the rotational angular positions of the dosage setting member and the dosing element or dosing and drive element pre-set in this way.

The dosing and drive device can operate manually, semi-automatically or fully automatically. In the first case, both the rotational dosing movement and the translational delivery movement are performed manually. In the second case, either the rotational dosing movement or the translational delivery movement is performed manually and the other movement is performed using motors or by means of another type of force application, for example by means of a spring force, when the user has triggered the corresponding movement using an activating or actuating handle or structure. In the third case, that of the fully automatic dosing and drive device, the dosing movement and the delivery movement are performed using

motors or by means of another force, for example a spring force. In this case, only the dosage is selected manually, for example by means of one or more buttons, and the delivery movement is likewise triggered by the user using a corresponding activating handle of its own. In most embodiments, the administering apparatus in accordance with the invention is equipped with a manual dosing and drive device, which is then referred to as a dosing and activating device. Thus, whenever a dosing and activating device is mentioned, it is therefore the manual embodiment which is being referred to. Where a dosing and drive device is mentioned, this is not intended to restrict the invention with respect to being manual, semi-automatic or fully automatic, but rather to comprise each of these embodiments. The term "dosing and activating module" is, however, used in connection with all the embodiments of the dosing and drive device.

The dosing and drive device can separately comprise a dosing element which performs the dosing movement and a drive element which performs the delivery movement. In some preferred embodiments, however, the dosing movement and the delivery movement are performed by the same body of the dosing and drive device which is therefore also referred to in the following as a dosing and drive element or dosing and activating element.

The product or substance to be delivered or administered may be a fluid, particularly a liquid, having a medical, therapeutic, diagnostic, pharmaceutical or cosmetic application. The product can for example be insulin, a growth hormone or also a thin or thick, pulpy food. An administering apparatus in accordance with the present invention may be employed in applications in which a user self-administers the product him/herself, as is, for example, common in diabetes therapy. However, its use in the field of in-patients or out-patients, by trained staff, is not excluded.

In the case of an injection apparatus, the product can be administered by means of an injection cannula or a nozzle (for needle-free injections). The product can be injected or infused subcutaneously or venously, or also intramuscularly. When administered by inhalation, the selected product dosage can be delivered from the reservoir into a chamber of the inhalation apparatus and vaporized for inhalation by means of a vaporizing means. Furthermore, oral

ingestion is conceivable, or administering via the esophagus, to name but a few administering examples.

In some preferred embodiments, the administering apparatus is semi-disposable. In this case, the front casing section is a support for a reservoir module which is disposed of or recycled once the reservoir has been emptied, and the rear casing section is a support for a dosing and activating module which can be repeatedly used in conjunction with a new reservoir module. Since the reservoir module can also be treated separately as a disposable module, it is also a separate subject of the invention. The dosing and activating module can also be also a separate subject of the invention. Equally, a system consisting of an administering apparatus and at least one reservoir module, which can replace the reservoir module of the apparatus once it has been used, forms a subject of the invention. The duplex design of the administering apparatus, divided into a portion provided for use only once and a portion provided for repeated use (semi-disposable), is advantageous for injection pens in particular, but also for inhalation apparatus or apparatus for orally ingesting a product or for artificial feeding.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates two portions of a reservoir module in accordance with a first embodiment of the present invention;

Figure 2 illustrates the reservoir module formed by the two portions of Figure 1;

Figure 3 illustrates a perspective view of an injection apparatus including the reservoir module of Figure 2, in accordance with the first embodiment, in a longitudinal section;

Figure 4 illustrates a portion of the injection apparatus of Figure 3;

Figures 5a-5c illustrate a mechanism holder of the reservoir module, in a longitudinal section and two views;

Figures 6a-6d illustrate a blocking device for a piston rod, mounted by the mechanism holder;

Figures 7a, 7b illustrate a piston rod in a longitudinal section and a front view;

Figures 8a-8c illustrates a latching block in a longitudinal section, a view and a top view;

Figure 9 illustrates a second embodiment of an injection apparatus of the present invention;

Figure 10 illustrates the cross-section A-A of Figure 9;

Figure 11 illustrates the cross-section B-B of Figure 9;

Figure 12 illustrates the cross-section C-C of Figure 9;

Figure 13 illustrates the cross-section D-D of Figure 9;

Figure 14 illustrates a perspective view of the mechanism holder of the second embodiment of the present invention;

Figure 15 illustrates the mechanism holder of Figure 14, in a view;

Figure 16 illustrates the cross-section A-A of Figure 15;

Figure 17 illustrates a perspective view of the dosage setting member of the second embodiment;

Figure 18 illustrates a longitudinal view of the dosage setting member of Figure 17;

Figure 19 illustrates the dosage setting member of Figure 17;

Figure 20 illustrates a top view of the dosage setting member of Figure 17;

Figure 21 illustrates a portion of the injection apparatus in accordance with Figure 3; and

Figure 22 illustrates a portion of the injection apparatus in accordance with Figure 9.

DETAILED DESCRIPTION

Figure 1 shows a view of a reservoir part 1 and a mechanism holder 3, which are connected to each other to form the reservoir module 10 shown in Figure 2.

In Figures 1 and 2, a piston rod can be seen which protrudes, on an end of the mechanism holder 3 facing away from the reservoir part 1, into the mechanism holder 3 and is coupled to, or mounted or carried by the mechanism holder 3 such that it can shift in an advancing direction pointing in the longitudinal axis L of the piston rod 4, towards a front end of the reservoir part 1 facing away from the mechanism holder 3. The reservoir part 1 is substantially a hollow cylinder which has a circular cross-section and comprises a connecting region at its front end for connecting to a needle holder for an injection needle. The reservoir part 1 serves to accommodate a reservoir container which in the exemplary embodiment is formed by an ampoule 2 which can be seen in the longitudinal section in Figure 3. An outlet at the front end of the ampoule 2 is sealed fluid-tight by a membrane. When the needle holder is fastened to the front end of the reservoir part 1, a rear portion of the injection needle pierces the membrane, such that a fluid connection between the tip of the hollow injection needle and the reservoir 2 is established.

Figure 3 shows the injection apparatus in its entirety, in a longitudinal section. A piston is accommodated in the ampoule 2 such that it can shift in the advancing direction towards the outlet formed at the front end of the ampoule 2. Shifting the piston in the advancing direction displaces product out of the ampoule 2 and delivers it through the outlet and the injection needle.

The piston is advanced by the piston rod 4 which pushes against the piston via its front end and thus moves the piston in the advancing direction when advanced itself. The piston rod 4 is held by the mechanism holder 3 such that it can be moved in the advancing direction once a certain resistance has been overcome, but not counter to the advancing direction. The piston rod 4 is prevented from moving backwards, counter to the advancing direction, by a blocking means 8. The blocking means 8 is axially fixed by the mechanism holder 3, i.e. it is held in the mechanism holder 3 such that it cannot be moved in and counter to the advancing direction. It is, however, mounted by the mechanism holder 3 such that it can be rotated about the longitudinal axis L. The blocking means 8 also generates the resistance which has to be overcome in order to move forwards.

The blocking means 8 is shown on its own in Figure 6. It is formed by a one-part annular element which, rotatable about the longitudinal axis L, abuts the mechanism holder 3 between two facing, spaced collars 3b which protrude radially inwards from an inner surface of the mechanism holder 3. The collars 3b form a fixing means for axially fixing the blocking means 8. How the blocking means 8 is mounted in the mechanism holder 3 is most clearly seen from the representation of the mechanism holder 3 in Figure 5.

A dosage setting member 9 is accommodated in the mechanism holder 3. The dosage setting member 9 is formed as a threaded nut and is in threaded engagement with an outer thread of the piston rod 4. The dosage setting member 9 is secured against rotating by the mechanism holder 3, but is guided such that it can move axially and linearly in and counter to the advancing direction. The piston rod 4 and the dosage setting member 9 form a spindle drive for selecting the product dosage to be administered.

The ampoule holder 1 and the mechanism holder 3 are connected to each other, secured against rotating and shifting, and together form the reservoir module 10 of the injection apparatus, said reservoir module 10 comprising the piston rod 4 held by the mechanism holder 3 by means of the blocking means 8, and the dosage setting member 9. The ampoule holder 1 and the mechanism holder 3 together form a front casing section of the injection apparatus. A rear casing section 11 is connected to said front casing section 1' in a positive lock. The rear casing section 11 forms the support for a dosing and activating element 12 and, together with the dosing and activating element 12 and parts of a latching means and other parts, forms a dosing and activating module 30 of the injection apparatus.

Except for the dosage setting member 9, the piston rod 4 and the blocking means 8, a dosing and activating device comprises the other components for selecting the product dosage and activating the injection apparatus. In particular, it comprises the dosing and activating element 12. The dosing and activating device further comprises a counting and indicating means 17 for counting and optically indicating the selected product dosage. Not least the counting and indicating means 17 makes the dosing and activating module 30 a high-grade and therefore expensive part of the injection apparatus. While the comparatively inexpensive reservoir module

10 is designed as a disposable module, the dosing and activating module 30 is intended for repeated use, with consistently new reservoir modules 10.

For selecting the product dosage, i.e., for dosing, the dosing and activating element 12 can be rotated about the longitudinal axis L and is furthermore mounted by the rear casing section 11 such that it can linearly shift along the longitudinal axis L, in and counter to the advancing direction. The dosing and activating element 12 is hollow cylindrical and surrounds the piston rod 4 via a front section. A rear section of the dosing and activating element 12 protrudes out beyond a rear end of the casing section 11. A rod-shaped dosing slaving means 13 is inserted into the dosing and activating element 12 from the rear, as far as a collar of the dosing and activating element 12 protruding radially inwards. Furthermore, at the rear end, a closure 14 is inserted into the dosing and activating element 12, as far as the dosing slaving means 13. The dosing slaving means 13 is axially fixed relative to the dosing and activating element 12 between the radially protruding collar of the dosing and activating element 12 and the closure 14. The dosing slaving means 13 is also connected, secured against rotating, to the dosing and activating element 12. For the purpose of dosing, the dosing slaving means 13 protrudes into the hollow piston rod 4 from the rear. The piston rod 4 comprises a connecting section 4a (Figure 4) which engages with the dosing slaving means 13 such that the piston rod 4 and the dosing slaving means 13 and therefore also the dosing and activating element 12 cannot be rotated relative to each other about the common longitudinal axis L, but can be moved relative to each other along the longitudinal axis L, in and counter to the advancing direction. For this purpose, the connecting section 4a is formed as a linear guide for the dosing slaving means 13.

A restoring means 16 elastically tenses the dosing and activating element 12 counter to the advancing direction, into the initial position shown in Figures 3 and 4. In the initial position, the product can be dosed by rotating the dosing and activating element 12 about the longitudinal axis L. Then, from the initial position, the selected product dosage can be delivered by axially shifting the dosing and activating element 12. The restoring means 16 is formed by a spiral spring acting as a pressure spring, which is accommodated in an annular gap around the dosing and activating element 12 and axially supported between a collar of the casing section 11 protruding radially inwards and a collar of the dosing and activating element 12 facing opposite and protruding radially outwards.

The blocking means 8 fulfils a double function. On the one hand, it ensures via its blocking elements 8a that the piston rod 4 cannot be moved back, counter to the advancing direction, relative to the mechanism holder 3 and therefore in particular relative to the piston accommodated in the ampoule 2. In its double function as a brake, the blocking means 8 furthermore prevents the piston rod 4 from moving forwards during the dosing process in which the dosage setting member 9 is moved axially, counter to the advancing direction, towards the dosing and activating element 12.

In the initial position shown in Figures 3 and 4, before dosing, the dosage setting member 9 abuts against a delivery stopper 3c (Figure 5) formed by the mechanism holder 3, in the advancing direction. The piston rod 4 is in permanent touching contact with the piston. For the purpose of dosing, the dosage setting member 9 is moved away from the delivery stopper 3c towards the dosing and activating element 12 by the threaded engagement with the piston rod 4 and the linear guide from the mechanism holder 3. This reduces a slight distance between a rear stopper area of the dosage setting member 9 and a front stopper area of the dosing and activating element 12, but on the other hand increases the slight distance between a front stopper area of the dosage setting member 9 and the delivery stopper 3c. The latter distance between the delivery stopper 3c and the dosage setting member 9 is the path length by which the dosage setting member 9 and – due to the threaded engagement – also the piston rod 4 are moved in the advancing direction in the course of the delivery movement of the dosing and activating element 12. The delivery stopper 3c forms a front translational stopper. During the delivery movement, the piston rod 4 pushes via its front end, which is formed by a plunger body connected to the piston rod 4 such that it cannot move in or counter to the advancing direction, against the piston and pushes the piston forwards in the advancing direction towards the outlet of the ampoule 2. The longitudinal axis L forms the rotational and translational axis of the movements which are performed for the purpose of dosing and delivering the product.

The distance which the dosage setting member 9 and the dosing and activating element 12 exhibit between each other during the dosing process when the dosage setting member 9 abuts against the delivery stopper 3c corresponds to the maximum product dosage which can be selected and delivered in the course of a delivery. The stroke movement of the dosing and

activating element 12 is of equal length for each delivery. Dosing merely sets the distance between the dosage setting member 9 and the delivery stopper 3c and therefore the path length which can be jointly traveled by the dosing and activating element 12 and the dosage setting member 9 in the course of delivery.

The braking function of the blocking means 8 and the braking engagement which exists between the piston rod 4 and the blocking means 8 for this purpose are clear from an overview of Figures 6 and 7. On the one hand, the blocking means 8 comprises two braking elements 8b for the braking engagement, which are each formed by an elastically flexing catch, like the blocking elements 8a before them. In the exemplary embodiment, the blocking means 8 is formed by a single annular element from which four elastic catches axially project on an abutting side. The catches are arranged in a uniform distribution over the circumference of the annular element. Two mutually opposing catches form the blocking elements 8a and the other two catches, likewise arranged mutually opposing, form the braking elements 8b.

The piston rod 4 accordingly comprises two returning blocking means 6, which are formed on the outer surface on opposing sides and extend in the longitudinal direction of the piston rod 4, and two advancing braking means 7, which likewise extend in the longitudinal direction of the piston rod 4 on mutually opposing sides. The thread of the piston rod 4 for the threaded engagement with the dosage setting member 9 is formed by four remaining threaded sections 5 which extend over almost the entire length of the piston rod 4. The returning blocking means 6 and the advancing braking means 7 are each formed by a row of teeth. However, while the teeth of the returning blocking means 6 are formed as serrated teeth, narrowing in the advancing direction and comprising blocking areas pointing backwards and extending transverse to the advancing direction, the two rows of teeth which form the advancing braking means 7 do not comprise blocking areas pointing forwards having a comparable blocking effect. The teeth of the advancing braking means 7 each exhibit a "softer" tooth profile as compared to the returning blocking means 6. For the braking engagement between the blocking means 8 and the advancing braking means 7 of the piston rod 4 is not intended to prevent the piston rod 4 from being advanced, but merely to make it more difficult, in order to ensure that the piston rod 4 is not moved in the advancing direction during dosing. The front sides of the teeth of the advancing braking means 7 and the rear sides of the braking elements 8b, which touch the front sides of the

teeth of the advancing braking means 7, are shaped such that a threshold force which is not reached during dosing has to be overcome in order to overcome the braking engagement. This threshold force is larger than the force required to move the teeth of the returning blocking means 6 over the blocking elements 8a in the advancing direction. The threshold force is preferably at least twice as large as the initial frictional force between the returning blocking means 6 and the blocking elements 8a. The frictional force between the latter also only increases gradually between two consecutive blocking engagements in the course of the advancing movement. The threshold force of the braking engagement, by contrast, has to be applied from one blocking engagement to the next, immediately at the beginning of the advancing movement, in each blocking engagement. The threshold force should not, however, be so large that it distracts the user during delivery.

An undesired advancing movement by the piston rod as a response to the movement by the dosage setting member 9 when selecting the dosage can in principle also be prevented by the blocking engagement of the blocking means 8 alone. However, such a movement is more reliably prevented because of the braking engagement than by the blocking engagement alone.

The connection between the reservoir module 10 and the dosing and activating module 30 is a positive lock. On the one hand, a latching engagement exists between the mechanism holder 3 and the casing section 11 which prevents relative movement in the axial direction. Beyond the latching engagement, the front casing section 1' and the rear casing section 11 are guided axially and linearly directly onto each other, in order to prevent relative rotating when connected or connected. The axial guides 3d of the mechanism holder 3, which together with one or more corresponding engagement elements of the rear casing section 11 form the linear guide, can be clearly seen in Figure 5. The axial guides 3d are formed by guide areas on guide ribs; they could also be formed by guide areas in axially extending recesses. In this way, axial guide channels are obtained. The guide ribs are axially tapered, such that insertion funnels leading into the guide channels are formed for the one or more engagement elements of the rear casing section 11. In order to even better center the casing sections 1' and 11 at the beginning of connecting, the guide ribs are also tapered in the radial direction. The one or more engagement elements of the rear casing section 11 is or are preferably formed like the axial sections 3d on the surface counter area, i.e. the inner surface area, of the rear casing section 11.

The latching engagement exists between a first, female latching element 3a of the mechanism holder 3 (Figure 5) and a latching ring 20 which is connected to the rear casing section 11 such that it can move radially but not axially. The latching ring 20 forms a second, male latching element 21 which radially engages directly with the first latching element 3a. A lock/latch connection exists between the first latching element 3a and the second latching element 21 which prevents the reservoir module 10 and the dosing and activating module 30 from moving axially relative to each other.

Figures 3 and 4 show the latching element 21 in latching engagement with the latching element 3a. The latching element 3a is formed by an annular stay and a groove which runs around the outer surface of the mechanism holder 3. The annular stay forms a rear side wall of the groove. The second latching element 21 is formed by a cam which protrudes radially inwards from the inner surface of the latching ring 20 and which in the latching engagement is pushed radially inwards over an inner surface area of the rear casing section 11, protruding into the accommodating latching element 3a, by a restoring means 24. The latching ring 20 is supported in its entirety in the radial direction on an inner surface area formed by the rear casing section 11, by means of the restoring means 24, such that the restoring means 24 pushes against the outer surface of the latching ring 20 roughly in a radial extension of the latching element 21. The latching ring 20 surrounds the mechanism holder 3 and can be moved in its entirety radially back and forth against the restoring force of the restoring means 24, such that the second latching element 21 can be moved in and out of latching engagement with the first latching element 3a. The rear casing section 11 forms a tight sliding guide for the radial movement of the latching ring 20. On its side radially opposite the latching element 21, the latching ring 20 forms an unlatching button 22 for the user. In order to radially guide the restoring means 24 formed as a pressure spring, a guide cam projects radially from the outer surface area of the latching ring 20 facing away from the latching element 21.

Two blocking cams 23, which press radially outwards against a latching block 25, furthermore project from the outer surface area of the latching ring 20, in the circumferential direction on both sides of said guide cam and axially behind the guide cam. Since the blocking cams 23 abut against the latching block 25, a radial movement of the latching element 21 – which

could result in the latching engagement being released – is prevented. The latching engagement between the latching elements 3a and 21 is thus secured by the latching block 25. The latching engagement is secured in every position of the dosing and activating element 12, except for a releasing position which the dosing and activating element 12 assumes at the end of its delivery movement. The releasing position therefore coincides with the foremost shifting position which the dosing and activating element 12 assumes when it abuts the dosage setting member 9 in the course of its delivery movement and the dosage setting member 9 for its part abuts against the delivery stopper 3c of the mechanism holder 3. Providing the dosing and activating module 30 is not yet connected to the reservoir module, a mechanical stopper for the dosing and activating element 12 is formed by a stopper element 31 of the dosing and activating device. In the exemplary embodiment, a reset holder ring which serves to reset the indicator 17 forms the stopper element 31. The dosing and activating element 12 abutting against said stopper element 31 defines the releasing position of the dosing and activating element 12 in this case, the releasing position defined by the stopper element 31 corresponding to that defined by the dosage setting member 9 abutting the delivery stopper 3c.

Figure 8 shows the latching block 25. In the exemplary embodiment, it is formed as one piece by a blocking slider. The latching block 25 comprises a plate-shaped main body which extends axially when assembled, as for example shown in Figure 4. At one end, a stay 26 projects at right angles from the main body. When assembled, the stay 26 extends radially as far as the dosing and activating element 12. The stay 26 serves to fasten the latching block 25 to the dosing and activating element 12 which for this purpose comprises two annular stays formed axially spaced on an outer surface area, which form the slaving means 15a and 15b. The front slaving means 15a simultaneously forms the support collar for the restoring means 16. In the annular space formed between the slaving means 15a and 15b, the latching block 25 protrudes in via its stay 26 and is tightly enclosed axially on both sides by the two slaving means 15a and 15b.

At a front end facing away from the stay 26, the main body of the latching block 25 is provided with an axial recess 27 which is open towards the front end of the latching block 25. In this way, blocking tongues 28 extending axially on both sides of the recess 27 are formed. The blocking cams 23 of the latching ring 20 are arranged such that each of said blocking cams 23 pushes against one of the blocking tongues 28, providing the dosing and activating element 12

does not assume the releasing position. When the latching block 25 moves axially, the restoring means 24 for the latching element 21 extends through the axial recess 27.

Indentation recesses 29 are furthermore formed in the main body of the latching block 25, and define the releasing position of the dosing and activating element 12. One indentation recess 29 is provided for each of the blocking cams 23. The position of the indentation recesses 29 is selected such that they only overlap the blocking cams 23, and thus allow the blocking cams 23 to be inserted, when the dosing and activating element 12 has been advanced into its releasing position.

It is clear that in the arrangement specifically selected in the exemplary embodiment, a single blocking cam 23 could also be provided and the latching block 25 accordingly comprise only one indentation recess 29 and possibly also only one blocking tongue 28. Furthermore, the latching block could in principle be produced together with the dosing and activating element 12 as one piece. Forming it as a separate part, however, offers advantages with regard to production, assembly and the dosing and activating element 12 cooperating with the piston rod 4. With respect to the installation length of the latching block 25, it should also be pointed out that the latching block 25 is supported, on its outer side facing away from the latching element 21, on an inner surface area of the casing 11. In this way, the stability of securing the latching engagement is increased. The casing 11 preferably forms an axial guide for the latching block 25.

The functionality of the injection apparatus is described in the following, wherein it is assumed that a new reservoir module 10 and a dosing and activating module 30 which has already been used at least once are assembled and a product is then delivered for the first time.

The dosing and activating module 30 and the new reservoir module 10 are aligned axially with respect to each other, such that their two longitudinal axes are flush with each other. The reservoir module 10 is then inserted via its rear end into the casing 11, which is open to the front, of the dosing and activating module 30.

This centers the casing section 1, 3 and the casing section 11 on the tapered ends of the guide ribs 3d of the mechanism holder 3. While being slid on, the two casing sections are guided

axially and linearly onto each other in a rotational angular position pre-set by the linear guide, until the casing sections 1' and 11 assume a connecting end position in which the latching engagement of the latching elements 3a and 21 can be established or can be set by itself.

The dosing and activating element 12 is locked in pre-set rotational angular positions relative to the rear casing section 11. The linear guide of the casing sections 1' and 11 and the rotational angular locking positions of the dosing and activating element 12 are adjusted to each other such that the engagement, secured against rotating, between the dosing and activating element 12 and the piston rod 4 is established in every locking position of the dosing and activating element 12 and every rotational angular position in which the casing sections 1' and 11 are linearly guided onto each other.

If the dosing and activating element 12 is situated in an axial position relative to the casing section 11 which is behind the releasing position, the latching element 21 is held in its radially innermost position by the latching block 25. In this position of the latching element 21, the dosing and activating module 30 and the reservoir module 10 cannot be slid onto each other up to the connecting end position and therefore also cannot be connected to each other, since the annular stay formed on the outer surface of the mechanism holder 3, which forms a part of the first latching element 3a, comes to rest abutting against the second latching element 21 first.

The annular stay can be reduced to a short radial protrusion in the tangential direction, if it is ensured that the casing sections 1' and 11 can only be assembled in the rotational angular position in which such a protrusion and the second latching element 21 come to rest in an axial flush. The annular stay or radial protrusion could also form the first latching element 3a alone, since the essential function of the first latching element 3a is to allow the connection between the reservoir module 10 and the dosing and activating module 30 to be established only when the dosing and activating element 12 assumes its releasing position. If this condition is fulfilled, then the dosing and activating element 12 would ensure, when the connection between the reservoir module 10 and the dosing and activating module 30 is established, that the dosage setting member 9 is situated in its dosing zero position in which it abuts the delivery stopper 3c of the mechanism holder 3.

In order to fulfil the condition described above, the user pushes the dosing and activating element 12 axially forwards relative to the rear casing section 11 as far as the releasing position. In this relative position between the rear casing section 11 and the dosing and activating element 12, the blocking cams 23 can be moved into the indentation recesses 29 of the latching block 25. The user therefore not only pushes the dosing and activating element 12 at least as far as the releasing position, but simultaneously also pushes the second latching element 21 out of latching engagement by means of the unlatching button 22. The reservoir module 10 can then be moved axially over the annular stay of the first latching element 3a and inserted further into the rear casing section 11. The user can let go of the unlatching button 22. As soon as the second latching element 21 overlaps the first latching element 3a, it snaps into the accommodating latching element 3a due to the force of the restoring means 24, such that the latching engagement is established. The reservoir module 10 and the dosing and activating module 30 are then connected to each other in a defined way with respect to the position of the dosage setting member 9 and the piston rod 4. If the dosage setting member 9 still exhibited a slight distance from the delivery stopper 3c before the latching engagement is established, this distance is eliminated due to the action of the dosing and activating element 12, required to establish the connection. A resultant delivery of product can be accepted and even desired, for the purpose of priming the injection needle. This preferably resets the counting and indicating means 17 to zero.

In the defined initial state brought about in this way, the user can dose the product. The product is dosed by rotating the dosing and activating element 12 about the longitudinal axis L and relative to the casing section 11. Since the dosing slaving means 13 is connected to the dosing and activating element 12, secured against rotating, and for its part engages with the piston rod 4, secured against rotating, the dosing and activating element 12 slaves the piston rod 4 during its rotational dosing movement. Due to the threaded engagement between the piston rod 4 and the dosage setting member 9 and the linear guide of the dosage setting member 9 by the mechanism holder 3, the dosage setting member 9 performs an axial, translational dosing movement, pre-set by the thread pitch of the reciprocal threaded engagement, towards the dosing and activating element 12. The dosing and activating element 12 forms a rear translational stopper 12c which limits the translational dosing movement of the dosage setting member 9 and thus defines the maximum delivery stroke which may be set.

The counting and indicating means 17 counts the dosage units corresponding to the rotational angular position of the dosing and activating element 12 and indicates it optically.

Once the desired product dosage has been selected, the dosing process is completed. The selected product dosage is delivered by means of the delivery movement, pointing in the advancing direction of the piston, of the dosing and activating element 12. In the course of its delivery movement, the dosing and activating element 12 abuts against the dosage setting member 9 and slaves it. When the dosage setting member 9 abuts against the delivery stopper 3c of the mechanism holder 3 in the course of the delivery movement, the delivery movements of the dosing and activating element 12 and the delivery of product are completed. Once the user lets go of the dosing and activating element 12, it is preferably moved counter to the advancing direction, back into a new initial position for dosing and delivering the product again, by the restoring means 16. The counting and indicating means 17 is preferably coupled to the dosing and activating element 12 such that it has in the meantime been reset back to zero. It possibly possesses means for counting and indicating the total product amount already delivered and thus the residue product amount remaining in the ampoule 2.

In order to detach the reservoir module 10 from the dosing and activating module 30, the dosing and activating element 12 is advanced as far as the releasing position, i.e. until it abuts against the dosage setting member 9. in this position, the user can release the latching engagement again by pushing onto the unlatching button 22, and separate the reservoir module 10 from the dosing and activating module 30.

Figures 9 to 13 shows a longitudinal section and four cross-sections of a second exemplary embodiment of an injection apparatus. The injection apparatus of the second exemplary embodiment is identical to that of the first exemplary embodiment with respect to the latch and latching block 25, such that reference is made in this regard to the description of the first embodiment. In particular, the latching block 25 of the second embodiment is identical to that of the first embodiment with respect to all its functional details. The same applies to the latching elements 3a and 21.

The latching ring 20 and the position of the blocking cams 23 relative to the latching element 21 and relative to the latching block 25 in the initial state of the apparatus can be seen particularly clearly in the cross-sections of Figures 10, 11 and 12, to which reference is made in this regard, also as representative for the first embodiment.

The injection apparatus of the second embodiment differs from the first embodiment in the engagement and the progression of movement of the components involved in dosing. Furthermore, the mechanism holder fulfils, in addition to the functions of the mechanism holder of the first embodiment, the function of positioning the dosage setting member in discrete rotational angular positions which may be changed relative to the mechanism holder, for the purpose of dosing. The blocking means of the second embodiment, by contrast, is embodied more simply than that of the first embodiment. Primarily, only the differences as compared to the first embodiment will be described in the following, wherein for components which are identical in their basic function to the components of the same name in the first embodiment but differ in details, numbers in the thirties with the same end digit, or exactly the same reference numerals as in the first embodiment, as used. Where no statements are made regarding the second embodiment, the corresponding statements regarding the first embodiment shall apply.

In the second embodiment, the dosing and activating element 32, which can be axially and linearly moved relative to the rear casing section 11 and rotated about the longitudinal axis L, is connected to the dosage setting member 39, secured against rotating. The dosing and activating element 32 and the dosage setting member 39 can be moved in and counter to the advancing direction, relative to each other and relative to casing sections 1' and 11. The piston rod 4 is held by a mechanism holder 3, secured against rotating. In cooperation with blocking elements of the blocking means 38, formed on the mechanism holder 3 as one piece, the returning blocking means 6, which is functionally identical to the first embodiment, prevents the piston rod 4 from moving counter to the advancing direction, but allows it to move in the advancing direction. The blocking elements simultaneously form the returning block and the rotational block for the piston rod 4. Furthermore, as previously in the first embodiment, the dosing and activating element 32 forms a sliding guide for the piston rod 4.

During dosing, the dosing and activating element 32 performs the same rotational dosing movement as the dosing and activating element 12 of the first embodiment. However, since the engagement is secured against rotating, the dosage setting member 39 is slaved during the rotational dosing movement. The threaded engagement between the piston rod 4 and the dosage setting member 39 is again comparable to that of the first embodiment, such that due to the rotational dosing movement and the threaded engagement with the piston rod 4, a stopper 39c formed by the dosage setting member 39 is moved, in the course of dosing, counter to the advancing direction, towards a front end of the dosing and activating element 32. As opposed to the first embodiment, the dosage setting member 39 thus completes a rotational dosing movement and a translational dosing movement relative to the front casing section during dosing, while the piston rod 4 remains stationary. Once dosing has been completed, the delivery movement of the dosing and activating element 32 advances the piston rod 4 by the path length which corresponds to the slight distance between a stopper area of the dosage setting member 39 and the delivery stopper 3c of the mechanism holder 3, set by the dosing.

The translational dosing movement of the dosage setting member 39 is limited counter to the advancing direction by a rear translational stopper 11c which is formed directly by the rear casing section 11 itself. In the second embodiment, too, the rotational and translational axis of the components involved in dosing and delivering the product forms the longitudinal axis L.

As in the first embodiment, the front casing section 1' forms a sliding guide for the dosage setting member 39. In order to form the sliding guide, an inner surface area of the mechanism holder 3 and an outer surface area of the dosage setting member 39 are in sliding contact with each other. The dosing and activating element 32 engages with an inner surface area of the dosage setting member 39, to form the connection, secured against rotating, between the dosage setting member 39 and the dosing and activating element 32.

In the second embodiment, the piston rod 4 comprises no braking means of its own beyond the returning blocking means 6. Rather, the front sides of the serrated teeth of the returning blocking means 6 also form the braking means on their own. The piston rod 4 of the second embodiment can, however, be replaced by the piston rod 4 of the first embodiment.

Accordingly, the mechanism holder 3 of the second embodiment would in this case also have to form at least one braking element, preferably both braking elements, of the first embodiment.

Figures 14 to 16 show the mechanism holder 3 of the second embodiment in a perspective representation, a side view and in the cross-section A-A indicated in the side view. As in the first embodiment, the mechanism holder 3 is embodied as a one-part sleeve part, preferably as a plastic injection molded part. It comprises a bulge 3e on the outer surface of a front sleeve section. The front sleeve section is plugged into the reservoir part 1 and locked non-detachably, at least for the user, to the reservoir part 1 by means of the bulge 3e.

The latching element 3a is formed on a middle sleeve section of the mechanism holder 3, as in the first embodiment.

A rear sleeve section, connected to the latching element 3a, forms a plurality of axial guides 3d on its outer circumference. The axial guides 3d are formed by guide ribs which protrude radially on the outer circumference of the rear sleeve section. More precisely, the axial guide formed by the axially extending, straight side walls of said guide ribs, such that – as in the first embodiment – axial guiding channels are obtained. The guide ribs protrude out from the middle sleeve section like fingers, as far as the rear end of the mechanism holder 3, where they taper off axially. The axial guide 3d serves to linearly guide the rear casing section 11 when the reservoir module 10 is connected to the dosing and activating module 30. As can be seen in Figure 9 and most clearly in Figure 11, engagement elements 11d project radially inwards from the inner surface area of the rear casing section 11, corresponding in number and adapted in shape. One engagement element 11d protrudes into each of the axial guides 3d and is linearly guided by the axial guide 3d when the front casing section 1' and the rear casing section 11 are slid into each other in order to be connected. In this way, it is ensured that there is no relative rotating between the front casing section 1' and the rear casing section 11 when the engagement, secured against rotating, between the dosing and activating element 32 and the dosage setting member 39 is established in the course of connecting.

Since the guide ribs taper off axially at their rear ends, and the guide channels are thus widened into insertion funnels, centering between the front casing section 1' and the rear casing

section 11, for the purpose of connecting, is made easier. The guide ribs also taper off at their ends radially with respect to the surface area of the mechanism holder 3, which makes centering the casing sections 1' and 11 into a rotational angular position pre-set by the axial guide 3d, relative to each other, even easier.

Just as the front casing section 1' and the rear casing section 11 are prevented from rotating relative to each other when sliding them into each other, the dosage setting member 39 is also fixed with respect to its rotational angular position relative to the front casing section 1', the dosage setting member 39 being detachably fixed in order to allow the rotational movement of the dosage setting member 39 necessary for dosing. In order therefore to enable the dosing movement of the dosage setting member 39 on the one hand, but to prevent an undesired dosing movement by establishing the connection between the front casing section 1' and the rear casing section 11, the dosage setting member 39 is fixed by the mechanism holder 3 in discrete rotational angular positions, by means of a releasable locking connection.

Figures 17 to 20 show individual representations of the dosage setting member 39. For forming the locking connection, a number of locking recesses 39g are formed on the outer surface area of the dosage setting member 39, distributed in regular separation over the circumference. Each of the locking recesses 39g is formed by a straight, axially extending furrow having a rounded contour running in its cross-section.

The mechanism holder 3 is provided with two locking projections 3g (Figures 15 and 16). The two locking projections 3g project radially inwards from an inner surface area of the mechanism holder 3 in the rear sleeve section of the mechanism holder 3. They are arranged diametrically opposed to each other. The respective surface region of the mechanism holder 3, on which one of the locking projections 3g is formed, forms a spring element 3f which is elastically flexible in the radially direction. Due to the elastic flexibility and the rounded shape of the locking projections 3g, in conjunction with the rounded profile of the locking recesses 39g, the locking engagement between the locking projections 3g and the opposing locking recesses 39g may be released. This is necessary for selecting the dosage. On the other hand, the locking engagement is however designed such that the dosage setting member 39 is rotationally angularly fixed sufficiently stable that there cannot be any undesired dosing movement of the dosage

setting member 39 when the front casing section 1' and the rear casing section 11 are connected, when the rotational coupling between the dosing and activating element 32 and the dosage setting member 39 is established. The locking connection between the mechanism holder 3 and the dosage setting member 39 has the advantageous side effect of a tactile signal during dosing. In order to maintain the favorable elasticity of the spring element 3f, the rear sleeve section of the mechanism holder 3 is cut away in the surface region in question, such that the spring element 3f is maintained as an annular segment extending in the circumferential direction which is axially free on both sides.

Axial guides 39d for the engagement, secured against rotating, between the dosage setting member 39 and the dosing and activating element 32 may likewise be seen in Figures 17, 18 and 20. The dosing and activating element 32 is provided with at least one engagement element, in order to obtain the axial linear guide, i.e. the rotational block, between the dosing and activating element 32 and the dosage setting member 39. The axial guides 39d are again guide channels formed by a number of guide ribs extending axially in a straight line. Each of the guide ribs tapers off axially and radially at its rear end facing the dosing and activating element 32, in order to make centering between the dosing and activating element 32 and the dosage setting member 39 easier, when the engagement, secured against rotating, is established. The same design is therefore used for the axial linear guide of the dosage setting member 39 and the dosing and activating element 32 as for the axial linear guide of the casing sections 1' and 11.

For the sake of completeness, reference is also made to the dosing thread 39a and the delivery stopper 39c of the dosage setting member 39, which can most clearly be seen in Figure 18.

Two rotational blocks are provided for the dosage setting member 39 which are active in the two axial end positions of the dosage setting member 39. Reference is additionally made in this regard to Figure 22.

In order to prevent the possibility of the piston rod 4 being moved back in response to a rotational dosing movement by the dosage setting member 39, rotational stoppers 39h are formed at a front end of the dosage setting member 39. In the front position, which the dosage setting

member 39 assumes directly after the product is delivered or before the dosage is selected, the rotational stoppers 39h engage with rotational counter stoppers 3h formed on the mechanism holder 3 (Figure 16). The rotational stoppers 39h axially project from a front abutting side of the dosage setting member 39, and the rotational counter stoppers 3h protrude from an axially facing abutting area of the mechanism holder 3 forming the delivery stopper 3c, axially opposed to the rotational stoppers 39h. The engagement between the rotational stoppers 39h and the rotational counter stoppers 3h is such that it allows a rotational dosing movement in a rotational direction, which causes a translational dosing movement of the dosage setting member 39 directed away from the delivery stopper 3c, but prevents a rotational dosing movement in the opposite rotational direction, in the front axial end position.

Furthermore, another pair of rotational stoppers and rotational counter stoppers is provided, which are formed and cooperate in basically the same way as the stoppers 3h and 39h. Said second pair of rotational stoppers are rotational stoppers 39i on the one hand, which axially project from a rear abutting area of the dosage setting member 39, and rotational counter stoppers 11i on the other, which axially protrude from the facing stopper abutting area of the rear translational stopper 11c towards the dosage setting member 39, which however cannot be seen in Figure 9 due to their small dimensions. In the rear end position, the rear pair of rotational stoppers 11i/39i prevents the possibility of the piston rod 4 being moved in the advancing direction in response to a dosing movement by the dosage setting member 39, directed against the rear translational stopper 11c.

The height, i.e., the axial length, of all the rotational stoppers 3h, 39h, 11i and 39i is adjusted to the thread pitch of the engaged dosing thread of the piston rod 4 and the dosage setting member 39. The rotational stoppers are axially sufficiently short that the rotational dosing movement which moves the dosage setting member 39 away from the respective translational stopper 3c or 11c is not impeded.

When assembling the components of the reservoir module 10, the dosage setting member 39 is screwed onto the piston rod 4 as far as a pre-set axial position, as may be seen from Figure 9. The piston rod 4, together with the screwed-on dosage setting member 39, is then inserted into the mechanism holder 3 from behind, until its blocking means 38 comes into blocking

engagement with the returning blocking means 6 of the piston rod 4 and furthermore the engagement, secured against rotating, between the rotational stoppers 39h of the dosage setting member 39 and rotational counter stoppers of the mechanism holder 3 is established. Even while being inserted into the mechanism holder 3, the dosage setting member 39 is axially and linearly guided by the mechanism holder 3 via the locking engagement between the locking projections 3g and the locking recesses 39g, until the dosage setting member 39 abuts the delivery stopper 3c of the mechanism holder 3. In this front end position of the dosage setting member 39 relative to the mechanism holder 3, the engagement, secured against rotating, between the rotational stoppers 3h and 39h has also already been established.

In this state, the mechanism holder 3 and a reservoir part 1, already fitted with a reservoir, are connected to each other.

In a following step, the rear casing section 11 of the completely assembled dosing and activating module 30 is slid onto the mechanism holder 3, wherein the mechanism holder 3 and the rear casing section 11 can be centered with respect to each other due to the axial guides 3d and the engagement elements 11d of the rear casing section 11 and, once centered, are axially and linearly guided onto each other due to the guide engagement. In the course of sliding the rear casing section 11 onto the mechanism holder 3, the dosing and activating element 32 comes into engagement, secured against rotating, with the dosage setting member 39, wherein here too a certain centering is also possible first, using a linear guide corresponding to the axial guides 3d and the engagement elements 11d.

The dosing and activating element 32 is in locking engagement with the rear casing section in discrete rotational angular locking positions and in the locking engagement, i.e., in the respective rotational angular locking position, is axially and linearly guided. The rotational angular difference between two consecutive rotational angular locking positions corresponds to one dosage unit. The linear guide between the mechanism holder 3 and the rear casing section 11 on the one hand, and the discrete rotational angular positions of the dosage setting member 39 relative to the mechanism holder 3 (locking projections 3g and locking recesses 39g) and the rotational angular locking positions of the dosing and activating element 32 relative to the rear casing section 11 on the other, are adjusted to each other such that the two casing sections 1' and

11 are always slid linearly over each other in a rotational angular position such that the dosage setting member 39 and the dosing and activating element 32 are also aligned relative to each other for their engagement, secured against rotating, such that there is no relative rotating between the components involved in dosing while the reservoir module 10 is connected to the dosing and activating module 30.

With respect to the other details of assembling, in particular of establishing the latching engagement, and of the functionality of the injection apparatus in accordance with the second embodiment, reference is made to the description of first embodiment.

Rotational blocks can also be provided in the injection apparatus in accordance with the first embodiment, which prevent undesired response movements by the piston rod 4 in the two axial end positions of the dosage setting member 9 of the first embodiment. Figure 21 shows the two rotational blocks, which are formed in the same way as the rotational blocks of the second embodiment. However, the rotational counter stoppers which in the second embodiment are formed on the casing sections 1' and 11 are formed in the first embodiment by the blocking means 8 on the one hand and the dosing and activating element 12 on the other. Thus, a number of rotational stoppers 8h are formed on the abutting side of the blocking means 8 axially facing the dosage setting member 9 and axially protrude towards the dosage setting member 9. Since the blocking means 8 is axially and immovably mounted by the front casing section 1' and connected, secured against rotating, to the piston rod 4, a rotational block for the rotational dosing movement between the piston rod 4 and the dosage setting member 9 is also obtained, via the front pair of rotational stoppers 8h/9h. The second pair of rotational stoppers is formed between the dosage setting member 9 and the rear translational stopper 12c. As in the second embodiment, a number of rotational stoppers 12i protrude axially towards the dosage setting member 9 from the abutting area of the translational stopper 12c axially facing the dosage setting member 9. As in the second embodiment, the dosage setting member 9 is provided on its rear side with rotational stoppers 9i which in the rear axial end position of the dosage setting member 9 engage with the rotational stoppers 12i. In the rear axial end position of the dosage setting member 9, the rear pair of rotational stoppers 9i/12i only allows the rotational dosing movement which causes a translational dosing movement of the dosage setting member 9 in the advancing direction.

In the foregoing description, embodiments of the present invention, including preferred embodiments, have been presented for the purpose of illustration and description. They are not intended to be exhaustive or to limit the invention to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiments were chosen and described to provide the best illustration of the principals of the invention and its practical application, and to enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth they are fairly, legally, and equitably entitled.